November 9, 2017

Smiths Medical ASD, Inc.
Mikael Evans
Regulatory Affairs Specialist I
6000 Nathan Lane North
Minneapolis, Minnesota 55442

Re: K172458
Trade/Device Name: HemoDraw® Plus Closed Blood Sampling System with LogiCal® Transducer Pressure Monitoring System
HemoDraw® Plus Closed Blood Sampling System with TranStar® Transducer Pressure Monitoring System
Regulation Number: 21 CFR 870.2850
Regulation Name: Extravascular Blood Pressure Transducer
Regulatory Class: Class II
Product Code: DRS
Dated: August 11, 2017
Received: August 14, 2017

Dear Mikael Evans:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172458

Device Name
HemoDraw® Plus Closed Blood Sampling System with LogiCal® Transducer Pressure Monitoring System
HemoDraw® Plus Closed Blood Sampling System with TranStar® Transducer Pressure Monitoring System

Indications for Use *(Describe)*

HemoDraw® Plus Closed Blood Sampling System with LogiCal® Transducer Pressure Monitoring System:

The HemoDraw® Plus Closed Blood Sampling Set with LogiCal® Pressure Monitoring System is a hemodynamic pressure monitoring and blood sampling system designed to allow easy withdrawal of blood samples from an arterial or central venous pressure monitoring line while maintaining a completely closed system.

HemoDraw® Plus Closed Blood Sampling System with TranStar® Transducer Pressure Monitoring System:

The HemoDraw® Plus Closed Blood Sampling Set with TranStar® Pressure Monitoring System is a hemodynamic pressure monitoring and blood sampling system designed to allow easy withdrawal of blood samples from an arterial or central venous pressure monitoring line while maintaining a completely closed system.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

ADMINISTRATIVE INFORMATION

Date of Preparation:	August 11, 2017
Submitter:	Smiths Medical 6000 Nathan Lane North Minneapolis, MN 55442 USA
Establishment Registration Number:	1526863 (Dublin)
Company Contact (Primary):	Mikael Evans Regulatory Affairs Specialist I Email: mike.evans@smiths-medical.com Office: 763-383-3047

PURPOSE

The purpose of this Traditional 510(k) premarket notification is to obtain FDA 510(k) clearance of the *HemoDraw® Plus Closed Blood Sampling System with LogiCal®/TranStar® Pressure Monitoring System* for the following changes:

- Design Update
  - Add distal stopcock sampling site option
- Labeling update:
  - Removal of "This device is for adult use only"
  - Add "MR conditional"

DEVICE INFORMATION

Trade Name	Closed Blood Sampling System
Device Name	HemoDraw® Plus Closed Blood Sampling System with LogiCal® Transducer Pressure Monitoring System HemoDraw® Plus Closed Blood Sampling System with TranStar® Transducer Pressure Monitoring System
Device Classification	Class II
Classification Name	Transducer, Blood-Pressure, Extravascular, 21 CFR § 870.2850 Product Code DRS

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PREDICATE DEVICE INFORMATION

Predicate Device Name	FDA Product Code	Predicate Device 510(k) Number
HemoDraw® Plus Closed Blood Sampling Set with LogiCal®/ TranStar® Transducer System	DRS 21 CFR § 870.2850	K163712

DEVICE DESCRIPTION

HemoDraw® Plus Closed Blood Sampling System with LogiCal® Pressure Monitoring System

The HemoDraw® Plus Closed Blood Sampling Set with LogiCal® Pressure Monitoring System is a closed blood Sampling System designed to allow easy and safe withdrawal of blood samples from an arterial and central venous invasive pressure monitoring line.

The LogiCal® Pressure Transducer mounting plate is intended for uses with the HemoDraw® Plus Closed Blood Sampling Set with LogiCal® Pressure Monitoring System. The LogiCal® monitoring set provides isolation between the fluid path connection to the patient and the transducer diaphragm.

This set includes a flush device that is intended for use in invasive blood pressure measurements that require continuous flow to maintain catheter patency. The flush device provides a controlled and constant fluid infusion at a rate determined by the patient's blood pressure and the fluid source pressure. With a total fluid source pressure equal to 300mmHg, the flush device delivers an average flow rate of 3ml/hour.

The device is supplied with a vented cap on the zeroing stopcock; this vented cap will allow air and saline to pass through and therefore can be kept in place when priming. To prevent the introduction of air into the system; after priming the vented cap should be replaced with a non-vented cap.

This device is intended for single use only and is provided sterile and fluid path non-pyrogenic unless package is damaged or opened.

HemoDraw® Plus Closed Blood Sampling System with TranStar® Pressure Monitoring System

The HemoDraw® Plus Closed Blood Sampling Set with TranStar® Pressure Monitoring System is a closed blood Sampling System designed to allow easy and safe withdrawal of blood samples from an arterial and venous invasive pressure monitoring line.

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The TranStar® Pressure Transducer mounting plate is intended for uses with the HemoDraw® Closed Blood Sampling Set with TranStar® Pressure Monitoring System. The TranStar® disposable monitoring set provides isolation between the fluid path connection to the patient and the transducer diaphragm.

This set includes a flush device that is intended for use in invasive blood pressure measurements that require continuous flow to maintain catheter patency. The flush device provides a controlled and constant fluid infusion at a rate determined by the patient's blood pressure and the fluid source pressure. With a total fluid source pressure equal to 300mmHg, the flush device delivers an average flow rate of 3ml/hour.

The device is supplied with a porous plug on the zeroing stopcock; this porous plug will allow air and saline to pass through and therefore can be kept in place when priming. To prevent the introduction of air into the system; after priming the porous plug should be replaced with a non-vented cap.

This device is intended for single use only and is provided sterile and fluid path non-pyrogenic unless package is damaged or opened.

INDICATIONS FOR USE

The *HemoDraw® Plus Closed Blood Sampling Set with LogiCal® Pressure Monitoring System* is a hemodynamic pressure monitoring and blood sampling system designed to allow easy withdrawal of blood samples from an arterial or central venous pressure monitoring line while maintaining a completely closed system.

The *HemoDraw® Plus Closed Blood Sampling Set with TranStar® Pressure Monitoring System* is a hemodynamic pressure monitoring and blood sampling system designed to allow easy withdrawal of blood samples from an arterial or central venous pressure monitoring line while maintaining a completely closed system.

COMPARATIVE ANALYSIS

There a minor physical differences between the subject and predicate device. The physical difference is the addition of a distal, to patient, stopcock sampling site and a distal stopcock positioning label to remind the user of the proper stopcock positions for priming and flushing the device. The proposed changes include an update to the indications for use to remove the "Adult use only" phrasing. Additionally, information and symbols will be added in the labeling for MR Conditional.

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TECHNOLOGICAL CHARACTERISTICS

The Smiths Medical HemoDraw® Plus Closed Blood Sampling System has the same technological characteristics as the predicate devices with the exception that the proposed version introduces a new distal, to patient, stopcock sampling site.

Section of Device	Device Name	SUBJECT DEVICE Smiths-Medical HemoDraw® Plus Closed Blood Sampling System (single and dual sampling site option)	PREDICATE DEVICE Smiths-Medical HemoDraw® Plus Closed Blood Sampling System (Single in-line patient sampling site) K163172	Comparison of Subject to Predicate Device for substantial equivalence
Device System	**Product Code**	DRS	DRS	Same
	Product Classification	FDA 21 CFR Class II	FDA 21 CFR Class II	Same
	Device Classification Name and 21 CFR	Transducer, Blood-Pressure, Extravascular, 21 CFR § 870.2850	Transducer, Blood-Pressure, Extravascular, 21 CFR § 870.2850	Same
	Patient Population	Various Populations	Adult	Similar – The subject device is expanding the indicated patient population.
	MR labeling	MR Conditional	MR Unsafe	Different – The subject conducted additional testing to label "MR conditional".

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Section of Device	Device Name	SUBJECT DEVICE Smiths-Medical HemoDraw® Plus Closed Blood Sampling System (single and dual sampling site option)	PREDICATE DEVICE Smiths-Medical HemoDraw® Plus Closed Blood Sampling System (Single in-line patient sampling site) K163172	Comparison of Subject to Predicate Device for substantial equivalence
Device System	**Intended Use**	The HemoDraw® Plus Closed Blood Sampling System is a hemodynamic pressure monitoring and blood sampling system designed to allow easy withdrawal of blood samples from an arterial or central venous pressure monitoring line while maintaining a completely closed system.	The HemoDraw® Plus Closed Blood Sampling System is a hemodynamic pressure monitoring and blood sampling system designed to allow easy withdrawal of blood samples from an arterial or central venous pressure monitoring line while maintaining a completely closed system.	Same
Device System	**Indications for Use**	The HemoDraw® Plus Closed Blood Sampling Set with LogiCal®/TranStar® Pressure Monitoring System is a hemodynamic pressure monitoring and blood sampling system designed to allow easy withdrawal of blood samples from an arterial or central venous pressure monitoring line while maintaining a completely closed system.	The HemoDraw® Plus Closed Blood Sampling Set with LogiCal®/TranStar® Pressure Monitoring System is a hemodynamic pressure monitoring and blood sampling system designed to allow easy withdrawal of blood samples from an arterial or central venous pressure monitoring line while maintaining a completely closed system. This device is for adult use only.	Similar – The subject device is removing the “Adult use only” indication.

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Section of Device	Device Name	SUBJECT DEVICE Smiths-Medical HemoDraw® Plus Closed Blood Sampling System (single and dual sampling site option)	PREDICATE DEVICE Smiths-Medical HemoDraw® Plus Closed Blood Sampling System (Single in-line patient sampling site) K163172	Comparison of Subject to Predicate Device for substantial equivalence
Device System	**Transducer types**	Reusable/Disposable	Reusable/Disposable	Same
	Hospital location use	ICU/OR	ICU/OR	Same
	Tubing	PVC	PVC	Same
Device System	**Biocompatibility**	Compatible materials ISO 10993-1	Compatible materials ISO 10993-1	Same
	Sterilization	Ethylene Oxide (EO) Sterile SAL 10^{-6} to end user	Ethylene Oxide (EO) Sterile SAL 10^{-6} to end user	Same
	Packaging Materials	Top Web: Dupont Uncoated 1073B TYVEK Bottom Web: Rexam 48 GA. Polyester / 0.0025" LDP	Top Web: Dupont Uncoated 1073B TYVEK Bottom Web: Rexam 48 GA. Polyester / 0.0025" LDP	Same
	Shelf-Life	3 Years	3 Years	Same
Reservoir	**Technological features**	Rigid, variable volume reservoir	Rigid, variable volume reservoir	Same
	Reservoir Size	5-mL/13-mL	5-mL/13-mL	Same
	Material	Polycarbonate	Polycarbonate	Same

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Section of Device	Device Name	SUBJECT DEVICE Smiths-Medical HemoDraw® Plus Closed Blood Sampling System (single and dual sampling site option)	PREDICATE DEVICE Smiths-Medical HemoDraw® Plus Closed Blood Sampling System (Single in-line patient sampling site) K163172	Comparison of Subject to Predicate Device for substantial equivalence
Sampling Site(s)	**Technological**	In-line Split Septum and Stopcock sampling site	In-line Split Septum	Same
	Number of Sampling site(s)	2 – Distal Stopcock and Proximal in-line sampling site	1 – in-line sampling site	Similar – The subject device as added a distal stopcock sampling site.
	Septum Housing	Silicone	Silicone	Same
Connectors	**Design by ISO Standard**	ISO 594-1: 1986 and ISO 594-2: 1998	ISO 594-1: 1986 and ISO 594-2: 1998	Same

SUMMARY OF PERFORMANCE TESTING

The HemoDraw® Plus Closed Blood Sampling Set with TranStar® and LogiCal® Pressure Monitoring Systems were evaluated via non-clinical performance testing to demonstrate the devices are as safe, as effective, and perform as well as or better than the predicate devices. All testing met pre-established specifications, and successfully demonstrated that the HemoDraw® Plus Closed Blood Sampling Set with TranStar® and LogiCal® Pressure Monitoring Systems performed as intended. A summary of the evaluation is provided below:

- Bench Testing was conducted per ISO 594-1: 1986 to ensure the *HemoDraw® Plus Closed Blood Sampling System* device meets the general requirements for conical fitting with a 6% (Luer) taper for syringes, needles and certain other medical equipment.

- Bench Testing was conducted per ISO 594-2: 1998 to ensure the *HemoDraw® Plus Closed Blood Sampling System* device meets the requirements for lock fittings for conical fitting with a 6% (Luer) taper for syringes, needles and certain other medical equipment.

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- Sterilization/Microbiology Validation was conducted to ensure product sterility to the end user for ISO 11135, AAMI TIR28 and ISO 11747.
- Material Bench Testing was conducted to ensure the *HemoDraw® Plus Closed Blood Sampling System* device materials met MR compatibility specifications
- Design Validation / Human Factors per ISO 62366 was conducted to ensure the subject device performance is acceptable for its intended use.
- Biocompatibility was assessed per ISO 10993-1 to ensure the *HemoDraw® Plus Closed Blood Sampling System* device materials are biocompatible to the indicated patient population

SUBSTANTIAL EQUIVALENCE CONCLUSION

Smiths Medical considers the subject device, *HemoDraw® Plus Closed Blood Sampling System with LogiCal®/TranStar® Pressure Monitoring System* performance to be substantially equivalent to the predicate device because, these devices are intended to be used in the same clinical manner; to monitor patient's blood pressure and allow patient blood sampling in closed system.

There are no significant difference in the intended use, mechanical and functional performance, and functional scientific technology. Smiths Medical demonstrates there are no new issues of safety and effectiveness raised due to the similarities/differences between the subject and predicate devices, as each are used to treat the same clinical condition and represent a similar design.

The subject device, *HemoDraw® Plus Closed Blood Sampling System with LogiCal®/TranStar® Pressure Monitoring System*, does not raise new questions of safety risks imposed on the patient or the device user.